

FORM PTO-1449 (MODIFIED)

LIST OF PATENTS AND PUBLICATIONS FOR  
APPLICANT'S INFORMATION DISCLOSURE  
STATEMENT

(Use several sheets if necessary)

ATTY. DOCKET NO.  
LMA 0113 PUS1SERIAL NO.  
UnknownAPPLICANT  
A. MARTIN LERNERFILING DATE  
Filed Herewith

GROUP

1c971 U.S. PTO  
10/060159  
01/30/02

## REFERENCE DESIGNATION

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
5	AA	4	5	4	4	6	3	4	10-01-85	Krenitsky	435	119	
5	AB	4	6	9	5	5	7	0	09-22-87	Krenitsky	514	261	
5	AC	4	8	9	7	3	9	4	01-30-90	Zimmerman, et al	514	258	
5	AD	4	9	5	7	9	2	4	09-18-90	Beauchamp	514	262	
5	AE	5	0	5	5	2	9	6	10-08-91	Wagle, et al	424	553	
5	AF	5	0	6	1	7	0	8	10-29-91	Krenitsky	514	262	
5	AG	5	0	7	9	2	5	2	01-07-92	Beauchamp	514	262	
5	AH	5	1	8	9	0	2	2	02-23-93	Bridge, et al	514	16	
5	AI	5	2	0	6	0	0	8	04-27-93	Loria	424	45	
5	AJ	5	2	1	3	1	0	6	05-25-93	Lerner	128	696	
5	AK	5	2	6	7	5	7	0	12-07-93	Preston	128	731	

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	AL													
	AM													
	AN													
	AO													
	AP													

## OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	AQ	<del>"A New Cardiomyopathy: A Pilot Study of Intravenous Ganciclovir in a Subset of the Chronic Fatigue Syndrome". A. Martin Lerner, et al. Depts. of Medicine, Wm. Beaumont Hospital, Wayne State Univ., Sch. of Med., Royal Oak, MI</del>
5	AR	"Perspectives on Interactions of Acyclovir with Epstein-Barr and Other Herpes Virus" Joseph S. Pagano, M.D., and Alok K. Datta, Ph.D. <i>Acyclovir Symposium-The American Journal of Medicine</i> 1982: 73: pp. 18-26.
5	AS	"Valacyclovir HCl (Valtrex) Provides Simplified Dosing and Increased Efficacy in the Treatment of Herpes Virus Infections" <i>Int. Pharm. Abstr.</i> 1994: 31:2244-5. Abstract No. 3111836

EXAMINER

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	AT	5	3	1	2	8	1	7	05-17-94	Snorrason	514	141	
	AU	5	3	5	7	9	6	8	10-25-94	Lerner	128	696	
	AV	5	4	0	5	8	5	0	04-11-95	Blumenkopf	514	262	
	AW	5	4	2	6	0	2	8	06-20-95	Levy et al	435	7.24	
	AX	5	4	6	1	0	4	2	10-24-95	Loria	514	182	
	AY	5	4	6	4	0	2	0	11-07-95	Lerner	128	696	
	AZ	5	4	9	1	1	5	0	02-13-96	Aoki et al	514	310	
	BA	5	5	3	8	8	5	6	07-23-96	Levy et al	435	7.24	
	BB	5	5	4	5	5	5	0	08-13-96	Grossberg et al	435	240.2	
	BC	5	5	4	5	6	7	0	08-13-96	Bissbort et al	514	562	

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		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION
													YES NO
	BD												
	BE												
	BF												

OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)		
9	BG	"The Chronic Fatigue Syndrome: A Comprehensive Approach to Its Definition and Study". Keiji Fukuda, M.D., et al ANNALS OF INTERNAL MEDICINE, Vol. 121, No. 12, pp. 953-959
5	BH	"Lack of Evidence for Infection with Known Human and Animal Retroviruses in Patients with Chronic Fatigue Syndrome", CLIN. INFEC. DISEASE 18, Suppl. 1, 1994, pp. S121-125
5	BI	"Long-Term Serological Follow-Up of Patients for Epstein-Barr Virus After Recovery from Infectious Mononucleosis", THE JOURNAL OF INFECTIOUS DISEASES, S. Horwitz, Vol. 151, No. 6, June, 1985, pp. 1150-1153
5	BJ	"Studies on Enterovirus in Patients with Chronic Fatigue Syndrome", J.W. Gow, et al CLINICAL INFECTIOUS DISEASES, 1994; 18 (Suppl. 1), pp. S126-129
5	BK	"Molecular Biology and Immunology of Cytomegalovirus", Paul D. Griffiths and Jane E. Grundy, BIOCHEM. J., (1987) Vol. 241, pp. 313-324
5	BL	"Herpes Simplex Encephalitis-Vidarabine Therapy and Diagnostic Problems", Richard J. Whitley, et al; THE NEW ENGLAND JOURNAL OF MEDICINE, Feb. 5, 1981; Vol. 304, No. 6, pp. 313-318

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y	BM	5	8	7	2	1	2	3	2/16/99	Lerner	514	258	
y	BN	6	2	5	8	8	1	8	7/10/01	Lerner	514	258	
	BO												
	BP												
	BQ												
	BR												

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		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	BS													
	BT													

OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)													
y	BU	"In Situ Detection of Human Cytomegalovirus Immediately-Early Gene Transcripts, etc." Tzyy-Choou Wu, et al. AIDS, 1992, Vol. 6, No. 8, pp. 777-785											
y	BV	"Cytomegalovirus as a Possible Cause of a Disease Resembling Infectious Mononucleosis" E. Klemola and L. Kaariainen, BRITISH MEDICAL JOURNAL, 1965, Vol. 2, pp. 1099-1102											
y	BW	"Infectious Mononucleosis", James C. Niederman, et al, JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION, 1968, Vol. 203, No. 3, pp. 205-209											
y	BX	"Medical Consequences of Persistent Viral Infection", Peter Southern and Michael B.A. Oldstone, NEW ENGLAND JOURNAL OF MEDICINE, Vol. 314, No. 6, pp. 359-367											
y	BZ	"Lack of Evidence for Infection with Known Human and Animal Retroviruses in Patients with Chronic Fatigue Syndrome", Walid Heneine, et al, CLINICAL INFECTIOUS DISEASES 1994; 18 (Suppl. 1), pp. S121-S125											
y	CA	"Repetitively Negative Changine T Waves at 24-h Electrocardiographic Monitors in Patients with the Chronic Fatigue Syndrome", A. Martin Lerner, et al; CHEST Vol. 104, No. 5, Nov. 1993, pp. 1417-1421											

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	CB						
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FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION
							YES NO
	CH						
	CI						

OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)		
✓	CJ	"Abnormal Left Ventricular Myocardial Dynamics in Eleven Patients with Chronic Fatigue Syndrome". CLINICAL NUCLEAR MEDICINE, Aug. 1994, Vol. 19, No. 8, pp. 675-677
	CK	<del>"Serum Antibody Titers to Epstein-Barr Virus and Cytomegalovirus in Patients with the Chronic Fatigue Syndrome in Birmingham, Michigan, 1987-1994. A. Martin Lerner, et al. Wm. Beaumont Hosp. Royal Oak, MI and Univ. of Michigan, Ann Arbor, MI"</del>
	CL	<del>"Abnormal Left Ventricular Myocardial Dynamics in Patients with the Chronic Fatigue Syndrome in Birmingham, Michigan, 1987-1994". A. Martin Lerner, et al. Wm. Beaumont Hospital, Royal Oak, MI; Wayne State Univ., Detroit, MI; Univ. of Michigan, Ann Arbor</del>
	CM	<del>"Cardiac Involvement in Patients with the Chronic Fatigue Syndrome as Documented with Holter and Biopsy Data in Birmingham, Michigan, 1991-1993". A. Martin Lerner, et al. Wm. Beaumont Hosp., Detroit; Wayne State Univ., Detroit; Univ. of Michigan, Ann Arbor</del>
	CN	<del>"A Unified Theory of the Cause of the Chronic Fatigue Syndrome", A. Martin Lerner, et al. Wm. Beaumont Hosp., Royal Oak, MI; Wayne State Univ., Detroit, MI</del>
✓	CO	"Immune Surveillance Against Epstein-Barr Virus". Denis J. Moss, et al. IMMUNOLOGY, Vol. 4, 1992, pp. 97-104

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							YES NO
	CV						
	CW						

OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)		
g	CX	"A Second Site for Epstein-Barr Virus Shedding: The Uterine Cervix", John W. Sixbey, et al. THE LANCET, Nov. 1986, pp. 1122-1124
g	CY	"Prolonged Inhibitory Effect of 9-(1,3-Dihydroxy-2-Propoxymethyl)Guanine Against Replication of Epstein-Barr Virus", Jung-Chung Lin, et al. JOURNAL OF VIROLOGY, April, 1984, Vol. 50, No 1, pp. 50-55
g	CZ	"Epstein-Barr Virus Replication in Oropharyngeal Epithelial Cells", John W. Sixbey, et al. THE NEW ENGLAND JOURNAL OF MEDICINE, Vol. 310, No. 19, 1984, pp.1225-1230
g	DA	"Chronic Epstein-Barr Virus Infection Associated with Fever and Interstitial Pneumonitis", Robert T. Schooley, et al. ANNALS OF INTERNAL MEDICINE, 1986, Vol. 104, pp. 636-643
g	DB	"Long-Term Serological Follow-Up of Patients for Epstein-Barr Virus After Recovery from Infectious Mononucleosis", Charles A. Horowitz, et al. THE JOURNAL OF INFECTIOUS DISEASES, Vol. 151, No. 6, June 1985, pp. 1150-1153
g	DC	"Is Neurally Mediated Hypotension an Unrecognised Cause of Chronic Fatigue?", Peter C. Rowe, et al. THE LANCET, Vol. 345, pp. 623-624

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													YES	NO
	DJ													
	DK													

OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)													
✓	DL		"Chronic Fatigue Syndrome", PRINCIPLES AND PRACTICE OF INFECTIOUS DISEASES-4TH ED., R. T. Schooley, 1995, pp. 1306-1310										
✓	DM		"Acyclovir Treatment of the Chronic Fatigue Syndrome", Stephen E. Straus, et al, THE NEW ENGLAND JOURNAL OF MEDICINE, Vol. 319, No. 26, pp. 1692-1698										
✓	DN		"The Chronic Fatigue Syndrome--One Entity or Many?", Morton N. Swartz, THE NEW ENGLAND JOURNAL OF MEDICINE, Vol. 319, No. 26, 1988, pp. 1726-1728										
✓	DO		"The Relationship Between Neurally Mediated Hypotension and the Chronic Fatigue Syndrome", Issam Bou-Holaigah, et al, JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION, Vol. 274, No. 12, pp. 961-967										
✓	DP		"A Cluster of Patients with a Chronic Mononucleosis-like Syndrome: Is Epstein-Barr Virus the Cause?", G.P. Holmes, et al, JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION, 1987, Vol. 257, No. 17, pp. 2297-2302										
✓	DQ		"Frequency of 'Chronic Active Epstein-Barr Virus Infection' in a General Medical Practice", Dedra Buchwald, et al, JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION, 1987, Vol. 257, No. 17, pp. 2303-2307										

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	DR						
	DS						
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							YES NO
	DX						
	DY						

OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)		
✓	DZ	"The Epstein-Barr Virus: Host Balance in Acute Infectious Mononucleosis Patients Receiving Acyclovir Anti-Viral Therapy". Q.Y. Yao, INT. J. CANCER, 1989, Vol. 43, pp. 61-66
✓	EA	"A Double-Blind, Placebo-Controlled Trial of Intravenous Immunoglobulin Therapy in Patients with Chronic Fatigue Syndrome". Andrew Lloyd, et al, THE AMERICAN JOURNAL OF MEDICINE, 1990, Vol. 89, pp. 561-568
✓	EB	"A Controlled Trial of Intravenous Immunoglobulin G in Chronic Fatigue Syndrome" P.K. Peterson, et al, THE AMERICAN JOURNAL OF MEDICINE, 1990, Vol. 89, pp. 554-560
✓	EC	"Chronic Fatigue Syndrome: A Working Case Definition", G.P. Holmes, et al ANNALS OF INTERNAL MEDICINE, 1988, Vol. 108, pp. 387-389
✓	ED	"Leukocyte-Transforming Agent: Prolonged Excretion by Patients with Mononucleosis and Excretion by Normal Individuals", H. Dean Golden, et al, THE JOURNAL OF INFECTIOUS DISEASES, 1973, Vol. 127, No. 4, pp. 471-473
✓	EF	"Enhanced Serological and Virological Findings of Epstein-Barr Virus in Patients with AIDS and AIDS-Related Complex", Ciro V. Sumaya, et al, THE JOURNAL OF INFECTIOUS DISEASES, 1986, Vol. 154, No. 5, pp. 864-870

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							YES NO
	EM						
	EN						

OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)							
J	EO		"Human Herpes Virus-6: Clinical Implications of a Recently Discovered, Ubiquitous Agent". Charles T. Leach, THE JOURNAL OF PEDIATRICS, 1992, Vol. 121, No. 2, pp. 173-181				
J	EP		"Summary: Viral Studies of Chronic Fatigue Syndrome". Dharam V. Ablashi, CLINICAL INFECTIOUS DISEASES, 1994:18 (Suppl. 1), pp. S130-S133				
J	EQ		"Epstein-Barr Virus-Specific IgA Serum Antibodies as an Outstanding Feature of Nasopharyngeal Carcinoma", Gertrude Henle, et al, INT. J. CANCER, 1976, Vol. 17, pp. 1-7				
J	ER		"Viral Latency and Transformation: The Strategy of Epstein-Barr Virus". George Klein, CELL, 1989, Vol. 58, pp. 5-8				
J	ES		"IgM Antibodies Specific for Epstein-Barr Virus in Infectious Mononucleosis Without Heterophil Antibodies". J. Nikoskelainen, et al, BRITISH MEDICAL JOURNAL, 1974, Vol. 4, pp. 72-75				
J	ET		"Repression of Human Cytomegalovirus Major Immediate Early Gene Expression in a Monocytic Cell Line". J. H. Sinclair, et al, JOURNAL OF GENERAL VIROLOGY (1992) Vol. 73, pp. 433-435				

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													YES	NO
	FA													
	FB													

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✓	FC		"Chest Pain and Palpitation", Eugene Braunwald, HARRISON'S PRINCIPLES OF INTERNAL MEDICINE (10th Ed.), (1983) pp. 25-31										
✓	FD		"Chronic Fatigue Syndrome-Information for Physicians", National Institute of Allergy and Infectious Diseases, National Institutes of Health, September, 1996 pp. 1-16										
✓	FE		"Acyclovir Treatment of the Chronic Fatigue Syndrome", Stephen Straus et al., 1988 New England Journal of Medicine, Dec. 29, 1988, Vol. 319, No. 26, pp. 1692-98										
✓	FF		"New Cardiomyopathy: Pilot Study of Intravenous Ganciclovir in a Subset of the Chronic Fatigue Syndrome", A. Martin Lerner et al., Departments of Medicine, Wm. Beaumont Hospital, Wayne State Univ., School of Medicine, 1997, 6:110-117										
✓	FG		"A Preliminary 6 Month Trial of Valacyclovir (VAL) in Chronic Fatigue Syndrome (CFS) Using the Epstein-Barr Virus (EBV), Cytomegalovirus (HCMV) Paradigm", A. Martin Lerner et al., Abstract for 36 <sup>th</sup> Annual Meeting of the Infectious Disease Society of America										
✓	FH		"The Human Herpesviruses", edited by B. Roizman, R.J. Whitley & C. Lopez, Raven Press Ltd., New York, 1993, Chapters 4, 5, 6 and 11										

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	FJ						
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							YES	NO
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	FP							

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not supplied	FQ	"A Preliminary Randomized Double-Blinded Controlled Six Month Trial of Valacyclovir in Chronic Fatigue Syndrome Using the Epstein-Barr Virus/Cytomegalovirus Paradigm." A. Martin Lerner, et al., 36TH Annual Meeting of the Infectious Diseases Society of America, 11/23-15/98, Denver, CO
	FR	"Stress/Rest Radionuclide Cardiac Ventriculography in Chronic Fatigue Syndrome." A. Martin Lerner, et al., presented in part at the 35th Annual Meeting of the Infectious Diseases Society of America, 9/15/97, San Francisco, CA.
	FS	<del>Lerner, A. Martin; Zervos, Marcus; Chang, C.H.; Beqaj, Savedin; Goldstein, James; O'Neill, William; Dworkin, Howard; Fitzgerald, Thomas; and Deeter, Robert G.; A Small Randomized Placebo-Controlled Trial of the use of Antiviral Therapy for Patients with Chronic Fatigue Syndrome. Clinical Infectious Diseases-2001-Vol-32, pages 1657-58.</del>
	FT	<del>Lerner, A. Martin; Zervos, Marcus; Chang, C.H.; Beqaj, Savedin; O'Neill, William; Dworkin, Howard; Fitzgerald, Thomas; and Deeter, Robert G.; Cardiac and Virologic Issues in Chronic Fatigue Syndrome Revisited; from Handbook of Infectious Diseases in press, Wiley Publishers. Editors are Jason, Leonard A.; Fennell, Patricia A.; and Taylor, Renee R.</del>
	FU	<del>Valcyte (valganciclovir hydrochloride tablets), pamphlet published and distributed by Roche Pharmaceuticals, Roche Laboratories, Inc., Nutley, NJ 07110, issued March 2001.</del>

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							YES	NO
	GB							
	GC							

## OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

<i>not considered</i>	GD	Brown, Frances; Banken, Ludwig; Saywell, Kay; and Arum, Inger; Pharmacokinetics of Valganciclovir and Ganciclovir Following Multiple Oral Doses of Valganciclovir in HIV- and CMV-Seropositive Volunteers, Adis International Limited; Clin Pharmacokinet 1999-Aug; 37-(2):167-176.
	GH	Jung, Donald, Ph.D.; and Dorr, Albert, Ph.D.; Single-Dose Pharmacokinetics and Valganciclovir in HIV- and CMV-Seropositive Subjects, Pharmacokinetics and Pharmacodynamics, J. Clin Pharmacol 1999; 39:800-804.
	GI	
	GJ	
	GK	

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DATE CONSIDERED

37/103

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.